

**IN THE
UNITED STATES COURT OF APPEALS
FOR THE FEDERAL CIRCUIT**

NATERA, INC.,

Plaintiff-Appellee,

v.

No. 24-1324

NEOGENOMICS LABORATORIES, INC.,

Defendant-Appellant.

**NATERA, INC.’S OPPOSITION TO
NEOGENOMICS LABORATORIES, INC.’S REQUEST
FOR AN ADMINISTRATIVE STAY**

INTRODUCTION

On February 5, 2024, Defendant-Appellant NeoGenomics Laboratories, Inc., moved this Court for a stay pending appeal and to expedite briefing on its appeal challenging a preliminary injunction entered on December 27, 2023. App.Dkt. 10-1.¹ In that motion, NeoGenomics requests an “immediate administrative stay” of the preliminary injunction pending resolution of NeoGenomics’s motion. *Id.* at vi. Natera respectfully submits this opposition to NeoGenomics’s request for an

¹ References to the docket refer to case No. 24-1324. NeoGenomics filed a separate notice of appeal, docketed in this Court as No. 24-1409. Natera does not oppose NeoGenomics’s request to consolidate these appeals. *See* App.Dkt. 10-1 at vi n.1.

immediate administrative stay. Natera will respond separately to NeoGenomics's requests for a stay pending appeal and expedited briefing. *See* App.Dkt.10-1 at 25.

NeoGenomics's request for an immediate administrative stay is unsupported by any argument. It is belied by NeoGenomics's month-long delay in seeking relief. And it is unnecessary to protect against any potential harm, especially considering the \$10,000,000 bond Natera posted securing the preliminary injunction. D.Ct.Dkt.197. Moreover, any such stay would cause Natera irreparable harm by defeating the protections provided by the district court's injunction. NeoGenomics's request for an administrative stay should be denied.

BACKGROUND

On July 28, 2023, Natera filed a complaint in the Middle District of North Carolina alleging NeoGenomics infringed two Natera patents, U.S. Patent Nos. 11,519,035 and 11,530,454, by selling RaDaR, a cancer detection test. D.Ct.Dkt. 1 at 1. Three days later, on July 31, 2023, Natera moved for a preliminary injunction. D.Ct.Dkt. 6 at 1.

On December 27, 2023—after full briefing, a 2.5-hour technology tutorial, D.Ct.Dkt. 162-2, and a full-day hearing, D.C.Dkt. 162-3—the district court granted Natera's motion for a preliminary injunction as to U.S. Patent No. 11,519,035 (the "'035 patent"). D.Ct.Dkt. 169. The injunction enjoined NeoGenomics from (1) making, using, selling, or offering for sale in the United States RaDaR or "any

assay or product not more than colorably different” from RaDaR and (2) “promoting, advertising, marketing, servicing, distributing, or supplying [RaDaR] so as to induce others’ infringement.” D.Ct.Dkt.171. NeoGenomics appealed, and this Court docketed the appeal on January 4, 2024. App.Dkt. 1.

On December 29, 2023, NeoGenomics moved the district court to stay the preliminary injunction pending appeal, D.Ct.Dkt. 177, and to modify the preliminary injunction, D.Ct.Dkt.179. NeoGenomics never asked the district court for immediate emergency interim relief from the injunction pending resolution of its motion to stay. NeoGenomics did, however, ask that the district court require Natera to post security for the injunction. *Id.* at 3-4. It also sought to clarify certain uses of RaDaR were excluded from the injunction’s scope. *Id.* at 5-7.

The district court agreed to some of NeoGenomics’s requests. On January 10, it entered an order requiring Natera to post \$10,000,000 in security, stating that the injunction would go into effect once the bond was posted. D.Ct.Dkt.193. At the same time, the district court granted part of NeoGenomics’s motion to modify, clarifying that NeoGenomics could perform certain RaDaR tests and use RaDaR in three trials for which NeoGenomics had already signed contracts. *Id.* at 6-7. The court held other portions of NeoGenomics’s motion under advisement. *Id.* On January 12, Natera posted the required security, causing the injunction to take effect. D.Ct.Dkt.197.

On February 2, the district court entered another order providing further clarification about whether the injunction applied (1) to “four potential contracts that are into the negotiation stage but not yet signed” and (2) to “future scientific reporting and publications developed from past work using RaDaR.” D.Ct.Dkt. 206 at 1. The district court decided that NeoGenomics could use RaDaR in three additional clinical trials, but prohibited NeoGenomics from using RaDaR for a fourth clinical trial. *Id.* at 4. The district court also explained that the injunction did not prohibit scientific reports and presentations that “are not promoting, advertising, or marketing RaDaR.” *Id.* at 3.

On February 5—over a month after its appeal was docketed in this Court on January 4, 2024, and weeks after the injunction took effect on January 12, 2024—NeoGenomics filed the instant motion for an immediate stay. App.Dkt. 10.

ARGUMENT

NeoGenomics’s request for an “immediate administrative stay” should be denied. Despite bearing the burden of justifying that extraordinary relief, NeoGenomics offers virtually no authority or reasoning supporting an immediate administrative stay while its stay request is under consideration. That, alone, merits denial. Moreover, NeoGenomics chose to delay for *over a month* in seeking such relief, never moving this Court or the district court for emergency interim relief since December 27, 2023, when the district court granted the motion for a preliminary

injunction. When the injunction became effective on January 12, NeoGenomics continued to sit on its hands without seeking any type of stay in this Court. That lack of urgency speaks volumes about whether there is any actual need for the extraordinary emergency relief NeoGenomics seeks. Finally, NeoGenomics fails to explain in its motion what immediate threatened harm it faces that would warrant an administrative stay—much less harm that would render Natera’s \$10,000,000 bond insufficient.

I. NEOGENOMICS OFFERS NO AUTHORITY FOR AN ADMINISTRATIVE STAY

“A stay is not a matter of right.” *Nken v. Holder*, 556 U.S. 418, 433-34 (2009) (quoting *Va. R. Co. v. United States*, 272 U.S. 658, 672-73 (1926)); see *Streck, Inc. v. Rsch. & Diagnostic Sys., Inc.*, 407 F. App’x 424 (Fed. Cir. 2010) (denying administrative stay). The requesting party “bears the burden of showing that the circumstances justify” a stay. *Nken*, 556 U.S. at 433-34. NeoGenomics flouts that rule. It omits any authority, argument, or rationale directed towards justifying the “immediate administrative stay” it seeks. App.Dkt. 10-1. Instead, it merely asks this Court to grant its preferred relief. *Id.* at 25. That request falls far short of justifying such an extraordinary remedy.

II. NEOGENOMICS’S MONTH-LONG DELAY SHOWS THAT THERE IS NO GENUINE NEED FOR AN ADMINISTRATIVE STAY

NeoGenomics’s delays in seeking immediate interim relief belie the need for an administrative stay. Administrative stays are “only intended to preserve the status

quo until the substantive motion for a stay pending appeal can be considered on the merits.” *Doe #1 v. Trump*, 944 F.3d 1222, 1223 (9th Cir. 2019). Such stays are procedural tools designed to address concerns that circumstances might change in a manner that eliminates the availability of relief. *See Nat’l Urban League v. Ross*, 977 F.3d 698, 702 (9th Cir. 2020) (rejecting administrative stay). NeoGenomics’s delay in seeking an administrative stay confirms no such concerns are present here.

The district court granted Natera’s motion for a preliminary injunction on December 27, 2023. D.Ct.Dkt.171. NeoGenomics’s appeal was docketed in this Court on January 4. App.Dkt.1. Yet NeoGenomics waited ***more than a month*** to raise its supposed need for “immediate” interim relief with either court. App.Dkt.10-1. It never sought emergency interim relief from the district court, despite moving that court for a stay pending appeal. It also never previously sought such relief from this Court, despite conceding that it has had the right to do so since at least January 12, when the injunction went into effect. App.Dkt.10-1 at vi; *see also* Fed. Cir. R. 8 (authorizing motion to stay injunction in this Court). If NeoGenomics can afford to wait several weeks to file its motion seeking “emergency” relief, it can afford to wait the reasonable period it will take this Court to consider its stay motion on the merits. NeoGenomics sat on its hands for weeks, and now asks this Court to displace the district court’s carefully drawn relief, reached

after extensive deliberation. App.Dkt.10-1 at 4. This Court should reject that unwarranted demand.

III. NEOGENOMICS FAILS TO SHOW ANY IMMEDIATE HARM ABSENT AN ADMINISTRATIVE STAY

NeoGenomics also fails to show that, absent an immediate administrative stay, it or the public will suffer immediate harm while this Court considers its stay request. That, too, forecloses the extraordinary relief.

The district court carefully crafted the injunction to avoid any immediate harm to NeoGenomics. The injunction has several exceptions that allow NeoGenomics to continue using RaDaR for certain uses. Specifically, the injunction carves out (1) certain clinical trials involving RaDaR, and (2) patients who were using RaDaR before the injunction issued. D.Ct.Dkt.193 at 6-7; D.Ct.Dkt.206 at 1. Those carveouts allow NeoGenomics to continue with several of its clinical studies and to continue providing services to patients who have already been using RaDaR. Those exceptions undermine any claim of immediate harm serious enough to justify an emergency administrative stay.

Second, the injunction took effect on January 12, 2024. NeoGenomics fails to explain how it or the public has been harmed since the injunction went into effect on that date. App.Dkt.10-1 at 16-21. NeoGenomics fails to explain how any specific patients have been prevented from accessing the testing services they desire. *Id.* at 21-24. Evidence reflected that “nine out of fourteen oncologists who use

tumor-informed MRD testing prefer” Natera’s product, Signatera. D.Ct.Dkt. 190 at 19 (citing D.Ct.Dkt. 100-1 at 19). Moreover, as the district court found based on the evidence in the record, “[a]nyone in need of a tumor informed MRD test will be able to get one from Natera,” as Natera “has the capacity to take on more customers,” and Signatera “is clinically validated for use with the same cancers as RaDaR.” D.Ct.Dkt. 169 at 20.

Having failed to show any serious harm over the multiple weeks since the injunction went into effect, NeoGenomics cannot explain why it or the public now faces some emergency threat of imminent harm so substantial that this Court should cast aside the district court’s carefully drawn injunction while the Court considers NeoGenomics’s stay request on the merits.

Finally, Natera has posted \$10,000,000 in security in the event that the injunction is reversed. D.Ct.Dkt. 197. That security is more than sufficient to protect NeoGenomics against any harm that it may suffer during the brief period its stay motion is pending.²

CONCLUSION

The Court should deny NeoGenomics’s request for an administrative stay.

² Natera will also address NeoGenomics’s inability to show likelihood of success when it addresses the request for a stay itself. NeoGenomics’s delay in seeking an immediate administrative stay, its failure to provide briefing justifying that extraordinary relief, and the absence of irreparable harm absent such relief are amply sufficient to deny the administrative stay request.

February 6, 2024

Respectfully submitted,

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FORM 9. Certificate of Interest

Form 9 (p. 1)
March 2023

**UNITED STATES COURT OF APPEALS
FOR THE FEDERAL CIRCUIT**

CERTIFICATE OF INTEREST

Case Number 24-1324

Short Case Caption Natera, Inc. v. NeoGenomics Laboratories, Inc.

Filing Party/Entity Natera, Inc.

Instructions:

1. Complete each section of the form and select none or N/A if appropriate.
2. Please enter only one item per box; attach additional pages as needed, and check the box to indicate such pages are attached.
3. In answering Sections 2 and 3, be specific as to which represented entities the answers apply; lack of specificity may result in non-compliance.
4. Please do not duplicate entries within Section 5.
5. Counsel must file an amended Certificate of Interest within seven days after any information on this form changes. Fed. Cir. R. 47.4(c).

I certify the following information and any attached sheets are accurate and complete to the best of my knowledge.

Date: 2/6/2024

Signature: /s/ Jeffrey A. Lamken

Name: Jeffrey A. Lamken

FORM 9. Certificate of Interest

Form 9 (p. 2)
March 2023

1. Represented Entities. Fed. Cir. R. 47.4(a)(1).	2. Real Party in Interest. Fed. Cir. R. 47.4(a)(2).	3. Parent Corporations and Stockholders. Fed. Cir. R. 47.4(a)(3).
Provide the full names of all entities represented by undersigned counsel in this case.	Provide the full names of all real parties in interest for the entities. Do not list the real parties if they are the same as the entities. <input checked="" type="checkbox"/> None/Not Applicable	Provide the full names of all parent corporations for the entities and all publicly held companies that own 10% or more stock in the entities. <input checked="" type="checkbox"/> None/Not Applicable
Natera, Inc.		

☐ Additional pages attached

FORM 9. Certificate of Interest

Form 9 (p. 3)
March 2023

4. Legal Representatives. List all law firms, partners, and associates that (a) appeared for the entities in the originating court or agency or (b) are expected to appear in this court for the entities. Do not include those who have already entered an appearance in this court. Fed. Cir. R. 47.4(a)(4).

☐ None/Not Applicable ☒ Additional pages attached

Quinn Emanuel Urquhart & Sullivan LLP	Williams Mullen	Kevin P.B. Johnson
Victoria Maroulis	Andrew J. Bramhall	Andrew R. Shores
Carmelle F. Alipio	Joshua Hiram Harris	Kevin Alexander Smith

5. Related Cases. Other than the originating case(s) for this case, are there related or prior cases that meet the criteria under Fed. Cir. R. 47.5(a)?

☒ Yes (file separate notice; see below) ☐ No ☐ N/A (amicus/movant)

If yes, concurrently file a separate Notice of Related Case Information that complies with Fed. Cir. R. 47.5(b). **Please do not duplicate information.** This separate Notice must only be filed with the first Certificate of Interest or, subsequently, if information changes during the pendency of the appeal. Fed. Cir. R. 47.5(b).

6. Organizational Victims and Bankruptcy Cases. Provide any information required under Fed. R. App. P. 26.1(b) (organizational victims in criminal cases) and 26.1(c) (bankruptcy case debtors and trustees). Fed. Cir. R. 47.4(a)(6).

☒ None/Not Applicable ☐ Additional pages attached

CERTIFICATE OF INTEREST – ADDITIONAL PAGES

4. Legal Representatives

Quinn Emanuel Urquhart & Sullivan LLP: Sandra Haberny and Tara Srinivasan

Williams Mullen: Robert Van Arnam

FORM 19. Certificate of Compliance with Type-Volume Limitations

Form 19
July 2020

**UNITED STATES COURT OF APPEALS
FOR THE FEDERAL CIRCUIT**

CERTIFICATE OF COMPLIANCE WITH TYPE-VOLUME LIMITATIONS

Case Number: 24-1324

Short Case Caption: Natera, Inc. v. NeoGenomics Laboratories, Inc.

Instructions: When computing a word, line, or page count, you may exclude any items listed as exempted under Fed. R. App. P. 5(c), Fed. R. App. P. 21(d), Fed. R. App. P. 27(d)(2), Fed. R. App. P. 32(f), or Fed. Cir. R. 32(b)(2).

The foregoing filing complies with the relevant type-volume limitation of the Federal Rules of Appellate Procedure and Federal Circuit Rules because it meets one of the following:

- ☒ the filing has been prepared using a proportionally-spaced typeface and includes 1692 words.
- ☐ the filing has been prepared using a monospaced typeface and includes _____ lines of text.
- ☐ the filing contains _____ pages / _____ words / _____ lines of text, which does not exceed the maximum authorized by this court's order (ECF No. _____).

Date: 2/6/2024

Signature: /s/ Jeffrey A. Lamken

Name: Jeffrey A. Lamken